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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: John Kevin COLLINS et al. Attorney Docket: P66877US2

Serial No.: 10/804,223

Group Art Unit: 1614

Filing Date: March 19, 2004

Examiner: n/a

For: USE OF LACTOBACILLUS SALIVARIUS

TRANSMITTAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an Information Disclosure Statement in the above captioned application.

XX Small Entity status of this application under 37 C.F.R. 1.9 and 1.27 has been established by a verified statement previously submitted.

XX Information Disclosure Statement, Form PTO-1449 and references.

The fee has been calculated as shown below:

Claims Remaining	Highest Number	Present Extra	Small Entity Rate Addit. (or) Fee	Other Than A Small Entity Rate Addit. Fee
After Amendment	Previously Paid For			
Total	45	- 45 = 0	x25 = \$	x 50 = \$
Indep.	4	- 4 = 0	x100 = \$	x 200 = \$
Total Additional Fee			\$	\$

 Credit Card Payment Forms in the amount of \$ are attached.

XX If a Petition for Extension of Time is necessary and the Petition and/or the check is not enclosed, this will act as the Petition and applicant herewith petitions the Commissioner to extend the time for response and charge any fees necessary under 37 CFR 1.17 (a) (1) - (5) to Deposit Account No. 06-1358. The Commissioner is also authorized to charge payment of any other additional fees associated with this communication or credit any overpayment to Deposit Account No. 06-1358. A duplicate copy of this sheet is attached.

JACOBSON HOLMAN, PLLC

Dated: February 8, 2005
400 Seventh Street, N. W.
Washington, D.C. 20004-2201
P66877US2
JCH/JC

By: John C. Holman

John C. Holman
Reg. No. 22,769

(1)



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

COLLINS et al.

Confirmation No.: 6092

Serial No.: 10/804,223

Group Art Unit: 1614

Filed: March 19, 2004

Examiner: Not Yet Assigned

For: USE OF LACTOBACILLUS SALIVARIUS

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

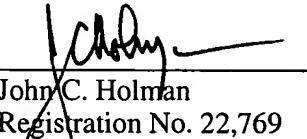
Sir:

As a means of complying with the duty of disclosure under 37 CFR §1.56, and in accordance with 37 CFR §§1.97 and 1.98, Applicants, through the undersigned attorney, submits this Information Disclosure Statement. The patents, publications or other information submitted herewith are listed on the attached Form PTO-1449 and copies are attached excluding U.S. patents and publications.

In accordance with 37 CFR §1.97(b)(3), this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits of the above-identified application.

Respectfully submitted,

JACOBSON HOLMAN PLLC

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LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

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U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (If Appropriate)
AA	4,347,240	8-31-82	MUTAI			
AB	4,435,389	3-6-84	MUTAI			
AC	5,032,399	7-16-91	GORBACH			
AD	5,711,977	1-27-98	YANG			
AE	5,834,423	11-10-98	KOKETSU			
AF	5,922,375	7-13-99	LUCHANSKY			
AG	6,077,504	6-20-00	CAVALIERE V. VESLEY			
AH	6,025,008	2-15-00	AKAHOSHI			
AI	6,132,710	10-17-00	PANIGRAHI			
AJ	6,368,591	4-9-02	CHEN			
AK	6,645,530	11-11-03	BORODY			
AL	6,746,671	6-8-04	STEIDLER			
ALA	5,443,826	8-22-95	BORODY			

FOREIGN PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	Translation (Yes)	(No)
AM	WO89/05849	6-24-89	WIPO				
AN	WO90/09398	8-23-90	WIPO				
AO	WO90/01335	2-22-90	WIPO				
AP	WO97/35596	10-2-97	WIPO				
AQ	WO98/00035	1-8-98	WIPO				
AR	WO98/35014	8-13-98	WIPO				
AS	WO99/51631	10-14-99	WIPO				
AT	WO99/62348	12-9-99	WIPO				
AU	WO00/42168	7-20-00	WIPO				
AV	WO01/37865	5-31-01	WIPO				
AW	WO01/85774	11-15-01	WIPO				
AX	WO02/058712	8-1-02	WIPO				
AY	WO02/083879	10-24-02	WIPO				
AZ	EP 384319B	4-28-99	EPO				

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						(Yes)	(No)
BA	EP508701B	7-10-96	EPO				
BB	EP904784A	3-31-99	EPO				
BC	EP1312667A	5-21-03	EPO				
BD	GB1503094	3-8-78	U.K.				
BE	RU2091075	4-20-98	RUSSIA			ABSTRACT	
BF	RU2055827	3-10-96	RUSSIA			ABSTRACT	
BG	JP05246864	9-24-93	JAPAN			ABSTRACT	
BH	JP9241173	9-16-97	JAPAN			ABSTRACT	
BI	SU1382467	3-23-88	RUSSIA				
BJ	DE19945746	4-19-01	GERMANY			ABSTRACT	
BK	KR2003063960	7-31-03	KOREA			ABSTRACT	
BL	RU2109054	4-20-98	RUSSIA			ABSTRACT	
BM	RU20001160	9-7-93	RUSSIA			ABSTRACT	

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EXAMINER
INITIALS

_____ BN Kim YC, Jeong HK, Kim SH, Moon IL, Kim BC, The properties of Bifidobacteria isolate from healthy Koreans, Korean J Dairy Sci, 20(3):191-204, 1998.

_____ BO Feeney, M., Morrissey, D., O'Sullivan, GC, Shanahan, F., Collins, JK. 1998. Lack of specific systemic immune response on oral consumption of probiotic lactobacilli. International Dairy Journal 8, No 5/6, 1998 Published Oct 16, 1998. Abstract from a meeting held in Cork, Ireland 30Sept -2 Oct 1997.

_____ BP Flynn, S. G.M. Thornton, D. Morrissey, J.K. Collins. (1998). Isolation and characterisation of the novel antibacterial proteins ABP-1 and ABP-118 from human isolates Lactobacillus salivarius ssp. salivarius UCC1 and UCC118. International Dairy Journal 8, No 5/6, 1998 Published Oct 16, 1998. Abstract from a meeting held in Cork, Ireland 30Sept -2 Oct 1997.

_____ BQ Charteris WP, Kelly PM, Morelli L, Collins JK. Antibiotic susceptibility of potentially probiotic Lactobacillus species. J Food Prot. 1998 Dec;61(12):1636-43.

_____ BR Charteris WP, Kelly PM, Morelli L, Collins JK. Antibiotic susceptibility of potentially probiotic Bifidobacterium isolates from the human gastrointestinal tract. Lett Appl Microbiol. 1998 May;26(5):333-7.

_____ BS Charteris WP, Kelly PM, Morelli L, Collins JK. Development and application of an in vitro methodology to determine the transit tolerance of potentially probiotic Lactobacillus and Bifidobacterium species in the upper human gastrointestinal tract. J Appl Microbiol. 1998 May;84(5):759-68.

_____ BT Collins JK, Thornton G, O'Sullivan G. Selection of probiotic strains for human applications. Int Dairy Journal. 1998, 8: 487-490.

_____ BU Gardiner G, Ross RP, Collins JK, Fitzgerald G, Stanton C. Development of a probiotic cheddar cheese containing human-derived Lactobacillus paracasei strains. Appl Environ Microbiol. 1998 Jun;64(6):2192-9.

_____ BV Gardiner, G., Collins, JK, Fitzgerald, G, Ross, P, Stanton, C. 1998. Characterisation of cheddar cheese harbouring probiotic lactobacillus adjuncts. International Dairy Journal 8, No 5/6, 1998 Published Oct 16, 1998. Abstract from a meeting held in Cork, Ireland 30Sept -2 Oct 1997.

_____ BW Kato D, et al "suppressive effects of the oral administration of L.casei on Type II collagen-induced arthritis inn DBA/1 mice" Life Sciences, Vol 63, No. 8 1998, pp 635-644.

_____ BX Morrissey D, Murphy L, Marteau P, Kiely B, Fitzgerald G, Daly C, O'Sullivan G, Shanahan F, Collins JK. (1998) Selection of a probiotic strain to modify human gut flora and a controlled trial of delivery and efficacy. Ir. J. Med Sci. 167; 8: 7 Abstract from meeting of Irish Society for Gastroenterology, June 12-13 1998

_____ BY Murphy, L., Thornton, G., Marteau, P., Morrissey, D., O'Sullivan, GC, Shanahan, F., Collins, JK. 1998. Long-term colonisation with Lactobacillus salivarius ssp. salivarius UCC118: A probiotic candidate. International Dairy Journal 8,595. No 5/6, Published Oct 16, 1998. Abstract from a meeting held in Cork, Ireland 30 Sept -2 Oct 1997.

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- ____ BZ O'Halloran S, Feeney M, Morrissey D, Murphy L, Thorton G, Shanahan F, O'Sullivan G, Collins JK. (1998) Adhesion of potential probiotic bacteria to human epithelial cell lines. International Dairy Journal 8, 596, No 5/6, 1998 Published Oct 16, 1998. Abstract from a meeting held in Cork, Ireland 30 Sept -2 Oct 1997.
- ____ CA O'Riordan, K, Condon, S, Fitzgerald, GF. 1998. Assessment of Bifidobacterium strains for microbial and exopolysaccharide production and evaluation of pulsed field gel electrophoresis as a method for identifying or discriminating between Bifidobacterial strains. International Dairy Journal 8,594.No 5/6, Published Oct 16, 1998. Abstract from a meeting held in Cork, Ireland 30 Sept -2 Oct 1997.
- ____ CB Collins J K, Probiotics and inflammatory bowel disease:animal models, Abstract from 3rd workshop Demonstration of the nutritional functionality of probiotic foods, FAIR CT96-1028, Functional Food Research in Europe, Haikko Manor, Finland 1-2 October 1998, pg 124.
- ____ CC Collins J K, Murphy L, O'Mahony L, Morrissey D, Feeney M, O'Halloran S, O'Donoghue M, Shanahan F, Kiely B, Fitzgerald G, O'Sullivan G, Demonstration of probiotic function in a double blind placebo controlled clinical trials in adults, Abstract from 3rd workshop Demonstration of the nutritional functionality of probiotic foods, FAIR CT96-1028, Functional Food Research in Europe, Haikko Manor, Finland 1-2 October 1998, pgs 40-41.
- ____ CD O'Riordan, K. and Fitzgerald, G.F. 1998. Evaluation of Bifidobacterium species for the production of antimicrobial compounds and assessment of performance in cottage cheese at refrigeration temperature. J. Appl. Microbiol. 85, 103-114.
- ____ CE Salminen S, Von Wright A, Morelli L, Marteau P, Brassert D, de Vos WM, Fonden r, Saxelin M, Collins JK, Mogensen G, Birkeland SE, Mattila-Sandholm T. (1998b) Demonstration of safety of probiotics. Int. Jnl. Food Micro. 44, 93-106.
- ____ CF Shanahan F, O'Sullivan GC, Collins JK. Genes, bacteria, and T cells: ingredients for inflammatory bowel disease. Gastroenterology. 1998 Dec;115(6):1595-1600.
- ____ CG Stanton C, Gardiner G, Lynch PB, Collins JK, Fitzgerald G, Ross RP. (1998) Probiotic Cheese. International Dairy Journal 8, 491-496.
- ____ CH LAN, Jinggang. Immunopotentiating Activity of Bifidobacterium and its Significance. Foreign Medical Sciences: Clinic Biochemistry & Medical Test 1998, Vol. 19(5): 231-233
- ____ CI Gionchetti et al "Microflora in the IBD Pathogenesis Possible Therapeutic Use of Probiotics". Gastroenterology International. 1st International Meeting on Intestinal Microflora 1998. Vol. 11. Suppl. 1, pages 108 to 110
- ____ CJ Steidler L., K. Robinson, L. Chamberlain, K.M Scholfield, E. Remaut, R.W.F. Le Page and J.M. Wells. Mucosal delivery of murine interleukin-2 (IL-2) and IL-6 by recombinant strains of Lactococcus lactis coexpressing antigen and cytokine. Infect. Immun., 1998; 66:3183-9.
- ____ CK Aranda R. et al. J. of Immunol. 1997; 158(7), 3464-3473

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____ CL Charteris WP, Kelly PM, Morelli L, Collins JK. Selective detection, enumeration and identification of potentially probiotic Lactobacillus and Bifidobacterium species in mixed bacterial populations. *Int J Food Microbiol.* 1997 Mar 18;35(1):1-27. Review.

____ CM Favier, C. et al; *Dig. Dis. Sci.* 1997;42:817-822

____ CN Gahan GC, Barrett JR, O'Sullivan GC, Shanahan F, Collins JK. Innate resistance to *Listeria monocytogenes* in tumour bearing mice. *J. Leucocyte Biology* 1997; 62(6): 726-732.

____ CO Leonard JP, Waldburger KE, Schaub RG, Smith T, Hewson AK, Cuzner ML, Goldman SJ. Regulation of the inflammatory response in animal models of multiple sclerosis by interleukin-12. *Crit Rev Immunol* 1997;17(5-6):545-53.

____ CP Lucey, M., and Fitzgerald, G.F. 1997. Developing fields in biotechnology:Biotechnology of lactic acid bacteria. *Food Science and Technology Today*, 11.230-233.

____ CQ Madsen, K. et al. *Gastroenterol.* 1997;112:A1030.

____ CR McFarland et al *Anaerobe*, Vol 3, No.2-3, 1997, pages 73-78

____ CS O'Riordan, K. and Fitzgerald, G.F. 1997. Determination of genetic diversity within the genus *Bifidobacterium* and estimation of chromosomal size. *FEMS Microbiol. Lett.* 156, 259-264.

____ CT Schmitt E, Rude E, Germann T. The immunostimulatory function of IL-12 in T-helper cell development and its regulation by TGF-beta, IFN-gamma and IL-4. *Chem Immunol* 1997;68:70-85.

____ CU Shanahan F, and O' Sullivan GC. Grand entry for *Listeria*. *Gastroenterology* 1997, 112: 1045-1046.

____ CV Singh, J. et al *Carcinogenesis* 1997;18:833-841

____ CW Mattila-Sandholm T, Demonstration project FAIR2 CT96-1028, VTT Symposium 173 Article from 2nd workshop Demonstration of the nutritional functionality of probiotic foods FAIR CT96-1028, Novel methods of probiotic research, Cork Ireland, 3 October 1997, pgs 11-15.

____ CX Collins K, Probiotic Lactobacilli - towards defining selection and functional criteria, VTT Symposium 167 Abstract from 1st workshop Demonstration of the nutritional functionality of probiotic foods FAIR CT96-1028, Selection and safety criteria of probiotics, Helsinki Finland, 15 November 1996, pg 27.

____ CY Arihara, K et al XP-002072786 School of Veterinary Medicine and Animal Sciences, 1996 The Society for Applied Bacteriology

____ CZ Bouhnik Y. et al; *Eur. J. Clin. Nutr.* 1996;50:269-273

____ DA Collins JK, O'Sullivan G, Shanahan F, Probiotic bacteria- interaction with the human immune system. *J. Roy. Soc. Med International Congress and Symposium Series* -209 Royal Society of Medicine Press (1996) 219:13-17

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INITIALS

— <u>DB</u>	Daly, C., Fitzgerald, G.F. and Davis, R. 1996. Biotechnology of lactic acid bacteria with special reference to bacteriophage resistance. In: Lactic Acid Bacteria : Genetics, Metabolism and Applications, (Venema, G., Huis in't Veld, J.H.J. and Hugenholtz, J., eds), pp. 3-14. Kluiver Academic Publishers, London, U.K.
— <u>DC</u>	Halpern, G.M., et al, The American Journal of Gastroenterology, Vol. 91, No. 8, 1996.
— <u>DD</u>	Huis in't Veld J, Shortt C. Selection criteria for probiotic micro-organisms. In: Leeds, A.R., Rowland, I.R. eds. Gut Flora and Health - Past, Present and Future. London: The Royal Society of Medicine Press Ltd., 1996:19-26
— <u>DE</u>	Takiguchi, R. et al. Bifidus - Flores, Fructus et Semina 1996;9:135-140
— <u>DF</u>	Collins JK, Selection of probiotic strains and potential therapeutic applications, from Book of Abstracts for European Commission Biotechnology and Fair Programmes Cork Ireland 22-26 October 1995.
— <u>DG</u>	Thornton G, Murphy L, Flynn S, O'Sullivan G, Shanahan F, Collins JK, Determination of stringent criteria essential to the survival/growth/colonisation of probiotic human intestinal tract bacteria, from Book of Abstracts for European Commission Biotechnology and Fair Programmes Cork Ireland 22-26 October 1995.
— <u>DH</u>	Lee et al., Trends in Food Science & Technology, Vol. 6,pp.241-245 (July 1995)
— <u>DI</u>	Medaglini D., G. Pozzi, T.P. King and V.A. Fischetti. Mucosal and systemic immune responses to a recombinant protein expressed on the surface of the oral commensal bacterium Streptococcus gordonii after oral colonization. Proc. Natl. Acad. Sci. USA, 1995;92:6868-72.
— <u>DJ</u>	Sarem-Damerdji Leila-ouassila, Sarem, Farzin, Marchal, Luc, Nicolas Jean-Pierre. "In vitro colonization ability of human colon mucosa by exogenous Lactobacillus strains. FEMS Microbiology Letters 131 (1995) 133-137.
— <u>DK</u>	Shanahan F. Pathogenic mechanisms in inflammatory bowel disease. In: Kasuya Y, Tsuchiya M, Matsuo Y, (editors) Gastrointestinal Function: Regulation and Disturbances Proceedings of the 13th symposium of the regulation and disturbances of gastrointestinal function, Tokyo, Nov 6, 1994. Excerpta Medica 1995;13: 13-28.
— <u>DL</u>	Thornton, G, O'Sullivan M, O'Sullivan G et al. Bile tolerance and bile salt hydrolase activity of lactobacilli and bifidobacteria isolated from the human intestine. Gastroenterology 108 (4) A928-A928 Suppl. S APR 1995
— <u>DM</u>	Yang H, Rotter JI. Genetics of inflammatory bowel disease. In Targan, SR. and Shanahan, F. eds. Inflammatory bowel disease: From bench to bedside. Williams and Wilkins 1994 (32-64).
— <u>DN</u>	Brink, B. ten M et al XP002072787 TNO Nutrition and Food Research, Department of Microbiology, Journal of applied Bacteriology 1994, 77, 140 148

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— DO Thornton G, O'Sullivan M, O'Sullivan G, Weerkamp A, Shanahan F, Collins JK, Bile acid tolerance and deconjugating activity of lactobiflora, Irish Journal of Medical Science, Supplement with Proceedings of the Irish Society of Gastroenterology Meeting 25 and 26th Nov 1994.

— DP Thornton G, O'Sullivan G, Collins JK The production of a novel anti-microbial substance by human intestinal microflora, Irish Journal of Medical Science, Supplement with Proceedings of the Irish Society of Gastroenterology Meeting 3 and 4th June 1994.

— DQ Thornton G, O'Sullivan G, Collins JK, Towards an understanding of the survival mechanism employed by the health promoting commensal flora of the human small intestine, Irish Journal of Medical Science, Supplement with Proceedings of the Irish Society of Gastroenterology Meeting 3 and 4th June 1994.

— DR Zhang, Houde et al. Treatment of Acute Enteritis with Oral Administration of Short-Term High-Dose Bifidobacteria. Chinese Journal of Microecology, Vol. 6, No. 6, p. 47 (1994)

— DS Kulkarni, N. and Reddy, B. Proc. Soc. Experim. Biol. Med. 1994;207:278-283.

— DT Shanahan F, O'Sullivan GC, Collins JK (1994). Immunosuppressive agents in inflammatory bowel disease. "Inflammatory Bowel Disease: Basic Research, Clinical Implications". (Eds. Sutherland L.R., Collins S.M., Martin F., Mc Leod R., Targan S.R., Wallace J.L. and Williams C.N.) Kluwer academic publishers, Dordrecht, Netherlands.1994; 367.

— DU Shanahan F, O'Sullivan GC, Collins JK. Immunosuppressive agents in inflammatory bowel disease: current status and future prospects. Can. J. Gastroenterology. 1994; 94(6): 383.

— DV Huis in't Veld, J.H.J.; Havenaar, R and Marteau, P. "Establishing a Scientific Basis for Probiotic R&D", Vol. 12. pp. 6-8 (January 1994)

— DW Walker, R.I. New strategies for using mucosal vaccination to achieve more effective immunization. Vaccine, 1994; 12: 387-400.

— DX Vaughan, E.E., Caplice, E., Looney, R., O'Rourke, N., Coveney, H., Daly, C. and Fitzgerald, G.F. 1994. Isolation from food sources, of lactic acid bacteria that produced antimicrobials. J. Appl. Bacteriol. 76, 118-123.

— DY ATTC Quarterly Newsletter, XP002072789, Vol. 13, No. 1, 1993

— DZ Thornton G, O'Sullivan M, O'Sullivan G, Collins JK, Human intestinal probiotic bacteria: Production of anti-microbial factors, Irish Journal of Medical Science, Supplement with Proceedings of the Irish Society of Gastroenterology Meeting 28 and 29th May 1993.

— EA O'Sullivan M, Thornton, G, Collins JK, O'Sullivan G, The human gut as a source of probiotic bacteria, - Myth or reality, Irish Journal of Medical Science, Supplement with Proceedings of the Irish Society of Gastroenterology Meeting 18,19, and 20th March 1993.

— EB Bouhnik, Y., Lait 1993; 73:241-247.

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INITIALS

— EC Klaenhammer, Tod R. XP-002072788, FEMS Microbiology Reviews 12 (1993) 39861993 Federation of European Microbiological Societies 0168-6445/93

— ED Marteau et al., FEMS Microbiology Reviews, Vol. 12, pp.207-220 (1993)

— EE O'Sullivan M, Thornton G, O'Sullivan G, Collins J.K, Probiotic bacteria in the Human GI tract (myth or reality) Irish Journal of Medical Science, Supplement with Proceedings of the Irish Society of Gastroenterology Meeting 4 and 5th December 1992.

— EF Adachi, The Lactic Acid Bacteria, Volume 1, "Lactic Acid Bacteria and the control of tumours", pp.233-261 (1992)

— EG Chauviere, G., M.H. Cocconier, S. Kermeis, J. Fourniat and A.L. Servin. Adhesion of human Lactobacillus acidophilus strains LB to human enterocyte-like Caco-2 cells. J. Gen. Microbiol. 1992; 138: 1689-1696

— EH O'Sullivan M, Thorton G, O'Sullivan G, Collins JK. Probiotics - myth or reality. Trends Food Sci. Tech. 1992; 3: 309-314.

— EI Tancrede, Eur. J.Clin. Microbiol, Infect. Dis., Vol. 11, pp.1012-1015 (November 1992)

— EJ Vaughan, E.E., C. Daly and G.F. Fitzgerald. 1992. Identification and characterization of helveticin V-1829, a bacteriocin produced by Lactobacillus helveticus 1829. J. Appl. Bacteriol. . 73, 299-308.

— EK de Waal Malefyt R, Haanen J, Spits H, Roncarolo MG, te Velde A, Figdor C, Johnson K, Kastelein R, Yssel H, de Vries JE. Interleukin 10 (IL-10) and viral IL-10 strongly reduce antigen-specific human T cell proliferation by diminishing the antigen-presenting capacity of monocytes via downregulation of class II major histocompatibility complex expression. J Exp Med 1991 Oct 1;174(4):915-24.

— EL Dekker, R, van der Meer, R, Olieman, C. Sensitive pulsed amperometric detection of free and conjugated bile acids in combination with gradient reversed-phase HPLC. Chromatographia 1991; 31(11/12): 549-553.

— EM O'Sullivan, M, O'Sullivan, G, Collins, JK, Isolation and selection of normal gut microflora for use as prophylactic probiotic agents, Irish Journal of Medical Science, Supplement with Proceedings of the Gastroenterology Meeting 7 and 8th June 1991

— EN Legrand-Defretin, R. et al., Lipids 1991; 26 (8), 578-583

— EO Mangan DF, Welch GR, Wahl SM. Lipopolysaccharide, tumor necrosis factor-alpha, and IL-1 beta prevent programmed cell death (apoptosis) in human peripheral blood monocytes. J Immunol 1991 Mar 1;146(5):1541-6.

— EP Toba et al., Letter in Applied Microbiology. Vol. 12,pp.228-231 (1991)

— EQ Wahl SM, Allen JB, Ohura K, Chenoweth DE, Hand AR, IFN-gamma inhibits inflammatory cell recruitment and the evolution of bacterial; cell wall-induced arthritis. J Immunol 1991 Jan 1;146(1):95-100.

— ER Chevalier, P., Roy, D., Ward, P. Detection of Bifidobacterium species by enzymatic methods. J. Appl. Bacteriol. 1990; 68: 619-624

EXAMINER	DATE CONSIDERED
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LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

APPLICANT:	COLLINS et al.	GROUP ART UNIT:	1614
SERIAL NO.:	10/804,223	ATTY. DOCKET NO.:	P66877US2
FILING DATE:	March 19, 2004	TODAY'S DATE:	February 8, 2005

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER INITIALS

____ ES Cicco NA, Lindemann A, Content J, Vandenbussche P, Lubbert M, Gauss J, Mertelsmann R, Herrmann F. Inducible production of interleukin-6 by human polymorphonuclear neutrophils: role of granulocyte-macrophage colony-stimulating factor and tumor necrosis factor-alpha. *Blood* 1990 May 15;75(10):2049-52.

____ ET Donnelly RP, Fenton MJ, Finbloom DS, Gerrard TL. Differential regulation of IL - production in human monocytes by IFN-gamma and IL-4. *J Immunol* 1990 Jul 15; 145(2):569-75

____ EU Gatanaga T, Hwang CD, Kohr W, Cappuccini F, Lucci JA 3d, Jeffes EW, Lentz R, Tomich J, Yamamoto RS, Granger GA. Purification and characterization of an inhibitor (soluble tumor necrosis factor receptor) for tumor necrosis factor and lymphotoxin obtained from the serum ultrafiltrates of human cancer patients. *Proc Natl Acad Sci U S A* 1990 Nov;87(22):8781-4.

____ EV Gilliland, *FEMS Microbiology Reviews*, Vol. 87, pp. 175-188 (1990)

____ EW Fuller, *Journal of Applied Bacteriology*, Vol. 66, pp.365-378 (1989)

____ EX Gautam, S. and R.S. de la Motte. 1989. *Proteolytic enzymes, a practical approach*. Chapter 3. R.J. Beynon and J.S. Bond(eds.), IRL Press, Oxford University Press;

____ EY Dinarello CA, Cannon JG, Wolff SM. New concepts on the pathogenesis of fever. *Rev Infect Dis* 1988 Jan-Feb;10(1):168-89.

____ EZ Ferrante A, Nandoskar M, Walz A, Goh DH, Kowanko IC. Effects of tumour necrosis factor alpha and interleukin-1 alpha and beta on human neutrophil migration, respiratory burst and degranulation. *Int Arch Allergy Appl Immunol* 1988;86(1):82-91.

____ FA Kim, *Cultured Dairy Products Journal*, "Characterization of Lactobacilli and Bifidobacteria as Applied to Dietary Adjuncts", pp.6-9 (August 1988)

____ FB Shanahan F, Leman B, Deem R, Targan S. In vivo primed cytotoxic T cells in inflammatory bowel disease. In *Inflammatory Bowel Disease: Current Status and Future Approach*. R.P. MacDermott (guest editor), International Congress Series 775, Elsevier Science Publishers B.V. (Biomedical Division), Amsterdam. *Excerpta Medica*, 1988;775:101-106.

____ FC Bachwich PR, Chensue SW, Larrick JW, Kunkel SL. Tumor necrosis factor stimulates interleukin-1 and prostaglandin E2 production in resting macrophages. *Biochem Biophys Res Commun* 1986 Apr 14;136(1):94-101.

____ FD Mestan J, Digel W, Mittnacht S, Hillen H, Blohm D, Moller A, Jacobsen H, Kirchner H. Antiviral effects of recombinant tumour necrosis factor in vitro. *Nature* 1986 Oct 30-Nov 5;323(6091):816-9.

____ FE Scardovi, V. (1986) *Bifidobacterium* in *Bergey's Manual of systemic bacteriology*, Vol. 2. Eds. Sheath, P.H., Main, N.S., Sharpe, M. and Holdt, J.G., Williams and Wilkins Publishers, Baltimore M.D., p1418.

____ FF Anand, S.K. et al. *Cult. Dairy Prods.* 1985;J. 2, 21-23.

EXAMINER	DATE CONSIDERED
----------	-----------------

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EXAMINER
INITIALS

- ____ FG Kawakami M, Ihara I, Ihara S, Suzuki A, Fukui K. A group of bactericidal factors conserved by vertebrates for more than 300 million years. *J Immunol* 1984 May;132(5):2578-81.
- ____ FH Tannock, Human Intestinal Microflora in Health and Disease. pp.517-539 (1983)
- ____ FI Tagg, JR, Dajani, AS, Wannamaker, LW. Bacteriocins of Gram positive bacteria. *Bacteriol Rev*. 1976; 40: 722-756.
- ____ FJ Dawson, R.M. 1969. pH and buffers. In *Data for Biochemical Research* p.138. R.M. Dawson, D.C. Elliot and K.M. Jones(eds.), Clarendon Press, Oxford.
- ____ FK Crabbe P.A., H. Bazin, H. Eyssen, and J.F. Heremans. The normal microbial flora as a major stimulus for proliferation of plasma cells synthesizing IgA in the gut. The germ free intestinal tract. *Int. Arch. Allergy Appl Immunol*, 1968; 34: 362-75.
- ____ FL O' Mahony L, Feeney M, Dunne C, O' Halloran S, Murphy L, Kiely B, O'Sullivan G, Shanahan F, Collins JK, Probiotic Bacteria and the Human Immune System, p63-70, 2000. In : *Proceedings of the British Nutrition Foundation/ Royal Society of Chemistry (Food Chemistry Group) Symposium Functional Foods '99, Claims and Evidence*. London UK. Proceedings from joint conference held by the British Nutrition Foundation and the Food Chemistry Group of the Royal Society of Chemistry on April 14-15 1999 at Wye College, University of London, Kent , UK
- ____ FM O'Mahony L et al "Probiotic human Bifidobacteria: selection of a new strain and evaluation in vitro and in vivo" *Gastroenterology*, Vol 118, no. 4, Suppl 2000
- ____ FN McBrearty S., Simpson, P.J., Fitzgerald, G., Collins, J.K., Ross R.P., and C. Stanton. "Probiotic Bifidobacteria and their identification using molecular genetic techniques". p97-107 In: "Functional Foods II- Claims and Evidence". Royal Society of Chemistry 2000, United Kingdom (eds Buttriss and Saltmarsh). Proceedings from joint conference held by the British Nutrition Foundation and the Food Chemistry Group of the Royal Society of Chemistry on April 14-15 1999 at Wye College, University of London, Kent , UK
- ____ FO Blum S, Reniero R, Schriffin EJ, Crittenden R, Mattila-Sandholm T, Ouwehand AC, Salminen S, Von Wright A, Saarela M, Saxelin M, Collins K, Morelli L. (1999) Adhesion studies for probiotics: need for validation and refinement. *Trends in Food Science and Technology* 10, 405-410.
- ____ FP Collins JK, Murphy L, O'Mahony L, Dunne C, O'Sullivan G, Shanahan F. (1999). A controlled trial of probiotic treatment of IL-10 knockout mice. *GASTROENTEROLOGY* 116 (4): G2981 Part 2 APR 1999
- ____ FQ Collins JK, O'Mahony L, Dunne C, et al. Probiotics and man - The host microbe interface *GASTROENTEROLOGY* 116 (4): G2982 Part 2 APR 1999
- ____ FR Dunne C, Murphy L, Flynn S, O'Mahony L, O'Halloran S, Feeney M, Morrissey D, Thornton G, Fitzgerald G, Daly C, Kiely B, Quigley EM, O'Sullivan GC, Shanahan F, Collins JK. Probiotics: from myth to reality. Demonstration of functionality in animal models of disease and in human clinical trials. *Antonie Van Leeuwenhoek*. 1999 Jul-Nov;76(1-4):279-92.

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EXAMINER
INITIALS

— FS Dunne C, O'Halloran S, O'Mahony L, et al. Epithelial adhesion of probiotic microorganisms in vitro and in vivo GASTROENTEROLOGY 116 (4): G3058 Part 2 APR 1999

— FT O'Mahony L, Feeney M, Halloran S, Murphy L, Kiely B, O'Sullivan G, Shanahan F, Collins JK, Consumption of probiotic bacteria ameliorates enterocolitis in IL-10KO mice, Irish Journal of Medical Science, Supplement with Proceedings of the Irish Society of Gastroenterology Meeting 11 and 12th June 1999.

— FU O'Mahony L, Feeney M, O'Halloran S, Murphy L, Kiely B, O'Sullivan G, Shanahan F, Collins JK, Probiotic treatment of enterocolitis in IL-10 KO mice, Sixth Symposium on Lactic acid bacteria, Veldhoven The Netherlands, 19-23 Sept 1999, Book of Abstracts.

— FV Gardiner G, Stanton C, Scanlon F, Wallace J, Collins JK, Fitzgerald G, Lynch PB, Ross RP, Cheddar cheese as a probiotic delivery system, Sixth Symposium on Lactic acid bacteria, Veldhoven The Netherlands, 19-23 Sept 1999, Book of Abstracts.

— FW Gardiner G, O'Sullivan E, Kelly J, Auty M, Ross RP, Collins JK, Fitzgerald G, Stanton C, Preparation of spray dried powders harbouring high levels of probiotic lactobacilli, Sixth Symposium on Lactic acid bacteria, Veldhoven The Netherlands, 19-23 Sept 1999, Book of Abstracts.

— FX O'Mahony L, Feeney M, Sheehan D, MacSharry J, Kiely B, O'Sullivan G, Shanahan F, Collins JK, UCC118 modulates proinflammatory cytokine production in vitro, Irish Journal of Medical Science, Supplement with Proceedings of the Irish Society of Gastroenterology Meeting 26 and 27th November 1999.

— FY Gardiner G, Stanton C, Lynch PB, Collins JK, Fitzgerald G, Ross RP. Evaluation of cheddar cheese as a food carrier for delivery of a probiotic strain to the gastrointestinal tract. J Dairy Sci. 1999 Jul;82(7):1379-87

— FZ Gardiner GE, Ross RP, Wallace JM, Scanlan FP, Jagers PP, Fitzgerald GF, Collins JK, Stanton C. Influence of a probiotic adjunct culture of Enterococcus faecium on the quality of cheddar cheese. J Agric Food Chem. 1999 Dec;47(12):4907-16 Mattila-Sandholm T, Blum S, Collins JK, Crittenden R, de Vos W, Dunne C, Fondén R, Grenov G,

— GA Isolauri E, Kiely B, Marteau P, Morelli L, Ouwehand AC, Reniero R, Saarela M, Salminen S, Saxelin M, Schriffin E, Shanahan F, Vaughan E, Von Wright A. 1999a Probiotics: Towards demonstrating efficacy. Trends Food Science and Technology 10, 393-399.

— GB Murphy L, Byrne F, Collins JK, Shanahan F, O'Sullivan G, Aranda R (1999a) Evaluation and characterization of probiotic therapy in the CD45R bhi transger model of colitis. Gastroenterology 116, G3382.

— GC Murphy L, Dunne C, Kiely B, Shanahan F, O'Sullivan G, Collins JK. In vivo assessment of potential probiotic lactobacillus salivarius strains: Evaluation of their establishment, persistence, and localization in the murine gastrointestinal tract. Microbial Ecology in Health and Disease 1999, 11:149-157.

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Reddy B.S "Possible mechanism by which pro and prebiotics influence carcinogenesis and tumor growth" J Nutr. 129, 1478S-1482S, 1999